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Director & State Health Officer

State of California—Health and Human Services Agency  
**California Department of Public Health**



EDMUND G. BROWN JR.  
Governor

**INFORMAL SOLICITATION (IS)**

Newborn and Prenatal Screening (NAPS) Laboratory  
Regions 1, 2 and 3

**TO ALL PROSPECTIVE RESPONDENTS**

January 15, 2014

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) (which includes the Genetic Disease Laboratory Branch (GDLB)) is soliciting eligible respondents with extensive background in laboratory testing. CDPH will award separate contracts for each of the three (3) geographic Regions. Respondent Laboratory must be physically located in the Region it will serve. To submit a proposal for these services, you must comply with the instructions contained in this document as well as the requirements stated in the Exhibits. In submitting your proposal response, you must comply with the instructions stated in this Informal Solicitation (IS).

**RESPONSE DUE DATE**

California Law requires Disabled Veteran Business Enterprise (DVBE) participation. CDPH policies require DVBE participation on all contracts exceeding \$10,000. Prospective proposers may need four weeks or more to complete this process; therefore it is advisable to begin this process promptly.

Interested Respondents are encouraged to submit a Letter of Intent to Bid, Section XIV, Sample Contract Forms/Exhibits, Exhibit J, by **January 24, 2014**. Failure to submit a Letter of Intent to Bid does not preclude any Respondents from participating in this process.

Regardless of postmark or method of delivery, GDSP must receive proposal response no later than **March 10, 2014, by 4:00 p.m. local time.**

**FUNDING LIMIT**

The proposed agreement is valid and enforceable only if sufficient funds are made available by the Budget Act of the appropriate fiscal year for the purpose(s) of the agreement.

In addition, the proposed agreement is subject to any additional restrictions, limitations, or conditions enacted by the Legislature, which may affect the provisions, terms, or funding of the agreement in any manner. If full funding does not become available, GDSP will either cancel the resulting agreement or amend it to reflect reduced funding and reduced activities. The estimated value of this entire project is up to \$13 million per year.

**Please read the document carefully.** In the opinion of the CDPH, this IS is complete and without need of explanation. However, if you have questions, or should you need any clarifying information, email your concerns to:

*Janice Byers*

California Department of Public Health/Genetic Disease Screening Program  
Center for Family Health  
850 Marina Bay Parkway, F175 Mail Stop 8200  
Richmond, CA 94804

Phone: (510) 412-5851 Fax: (510) 412-1556  
E-mail address: [Janice.Byers@cdph.ca.gov](mailto:Janice.Byers@cdph.ca.gov)

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## **I. Background and Purpose**

Pursuant to Health and Safety Code Section 125001(a) the legislature has mandated that the California Department of Public Health (CDPH) establish a program for the provision of genetic disease testing and has authorized CDPH to contract with qualified laboratories to perform this new state testing function.

It is the policy of CDPH, Center for Family Health, Genetic Disease Screening Program (GDSP) to make every effort to detect, as early as possible, heritable disorders leading to possible developmental delay, morbidity and mortality.

Regulations pursuant to Sections 12500, 125050 and 125070 of the Health and Safety Code, and Sections 6500 through 6508 and 6521 through 6531 of Title 17, California Code of Regulations (CCR) provide for newborn screening of each child born in California for amino acid disorders, fatty acid disorders, organic acidemias, galactosemia, primary congenital hypothyroidism, sickling hemoglobinopathies, cystic fibrosis, biotinidase deficiency, congenital adrenal hyperplasia and numerous other disorders.

Contractor screening for these rare disorders is accomplished most efficiently and at the lowest cost by large scale testing by a small number of laboratories. The Newborn Screening Program (NBS) in California encompasses screening approximately 500,000 newborns yearly using seven tests for each newborn, totaling more than three million individual tests. The California Prenatal Screening Program (PNS) currently encompasses screening the 1<sup>st</sup> and 2<sup>nd</sup> trimester specimens of approximately 360,000 pregnant women each year totaling nearly two million individual tests. GDSP has designed the Contractor programs to assure timely and accurate testing. Newborn and Prenatal Screening (NAPS) laboratories provide seven-day-a-week operation, including holidays with on-site Contractor supervisors.

Currently, a majority of the services solicited in this IS are provided by seven (7) laboratories throughout the State of California. As those existing contracts phase out, GDSP intends to execute the contracts awarded resulting from this IS. The GDSP intends to make a single agreement award in three (3) geographic Regions statewide to the most responsive and responsible Respondent receiving the best score. This IS is open to all eligible firms and/or individuals that meet the qualification requirements.

Depending on the transition period needed to ramp down on the existing NAPS Laboratories, and the time needed to ramp up the new Contractor in the respective Region, the Contractor may not begin the newborn and prenatal panel testing until CDPH directs the Contractor when panel testing will begin. It will begin no earlier than July 1, 2014 and no later than December 31, 2014. It is CDPH's current expectation that the winning Contractor laboratory will begin transition activities from July 2014 to September 2014. CDPH expects the NAPS laboratories would be fully consolidated and begin newborn and prenatal testing by September 2014.

At contract award, the winning Contractor laboratory must have the full set of operational equipment, the facility and proposed Key Staff on board. Should there be a delay in panel testing from July 1, 2014 the Contractor must maintain the proposed facility, fully operational equipment and Key Staff proposed at contract award. The laboratory can bid the monthly costs for maintaining these Key Staff Supervisory Personnel in Section XIII, Attachments/ Sample Exhibits/Appendices, Attachment 1a-Cost Proposal Summary and Instructions.

The CDPH will provide four (4) weeks' notice to the winning Contractor laboratory of the anticipated full consolidation and start of newborn and prenatal panels testing date. During these four (4) weeks, the winning Contractor laboratory must also successfully complete the

validation activities as outlined in Section XV, Program Appendices, Appendix 16, Required Validation Activities.

The resulting agreement will be of no force or effect until it is signed by both parties. Contractor is hereby advised not to commence performance until all approvals have been obtained. If performance commences before all approvals are obtained, said services may be considered to have been volunteered.

## **II. Agreement Terms**

The term of the resulting agreement is expected to be 36 months and is anticipated to be from **July 1, 2014** through **June 30, 2017**. There will be a transition/startup period prior to the testing of actual patient specimens; beginning when the winning Contractor is announced up to the start of testing actual patient specimens. The contractor will be required to participate in training and validation activities in order to make the laboratory ready for testing. The contractor will need to meet the quality assurance requirement of GDSP prior to engaging in patient sample testing and pass the quality assurance requirements on a continuous basis. The contractor will not be reimbursed for the activities prior to the start of patient specimen testing and all Contractor funds to support the transition/start-up period should be factored into the one time start-up cost. GDSP reserves the right to extend the term of the resulting agreement as necessary to complete or continue the services. Agreement extensions are subject to satisfactory performance, and funding availability.

## **III. Respondent's Questions**

Respondents shall immediately notify GDSP if clarification is needed regarding the services sought or questions arise about the IS and/or its accompanying materials, instructions, or requirements. Respondents shall submit questions in writing and transmit them to GDSP as instructed below. At its discretion, GDSP reserves the right to contact an inquirer to seek clarification of any inquiry received.

Respondents that fail to report a known or suspected problem with this IS and/or any accompanying materials or fail to seek clarification and/or correction of this IS and/or any accompanying materials shall submit a Response at their own risk. In addition, if awarded the agreement, the successful contractor shall not be entitled to additional compensation for any additional work caused by such problem, including any ambiguity, conflict, discrepancy, omission, or error.

### **A. What to Include in an Inquiry**

An inquiry, including those requesting clarification about a specific IS requirement must include the Respondent's name, name of the laboratory, mailing address, email address, area code and telephone number, and fax number. A description of the subject or issue in question or discrepancy found, IS section, page number or other information that may be useful in identifying the specific problem or issue questioned and remedy sought, if any. Any additional requirements shall be issued in the form of an addendum to all potential respondents.

A Respondent with an inquiry relating to sensitive issues or proprietary aspects of the Response may submit individual questions that are marked "Confidential." The Respondent must include with its inquiry an explanation as to why they believe questions marked 'Confidential' are sensitive or surround a proprietary issue. The CDPH accepts the inquiry as 'Confidential' and shall not share the inquiry and subsequent response with other Respondents.

## B. Question Deadline

Submit written questions and inquiries no later than the date and time stated in Section IV, Key Action Dates.

At its discretion, GDSP may accept questions or inquiries after the question deadline.

## C. How to Submit Questions

All questions must be submitted via email. Submit questions or inquiries by using the Auto Form titled: IS Questions-Submission Form to both the following email addresses: [janice.byers@cdph.ca.gov](mailto:janice.byers@cdph.ca.gov) and [tranisha.parker@cdph.ca.gov](mailto:tranisha.parker@cdph.ca.gov). The email reference line will read **Questions Regarding the GDSP NAPS Lab IS**.

## D. Verbal Questions

GDSP shall not accept any verbal questions and inquiries.

# IV. Key Action Dates

This informal solicitation timeline is subject to change. GDSP reserves the right to adjust any date and/or time as necessary. Date and time adjustments will be emailed to respondents.

Event	Due Date	Time (if applicable)
Release of Informal Solicitation	January 15, 2014	N/A
Letter of Intent To Bid Due	January 24, 2014	4:00 p.m.
Questions Due	January 31, 2014	4:00 p.m.
Response Submission Due date and time	March 10, 2014	4:00 p.m.
Anticipated Contract Award	April 15, 2014	N/A
Contract Proposed Effective Date	July 1, 2014	N/A

# V. Respondent's Response Requirements

## A. Executive Summary

The proposal response must include an Executive Summary of one to two pages in length which describes:

- How this program fits into the Respondent's goals and the Respondent's capabilities;
- What is the Respondent's plan to integrate the work described in this Informal Solicitation with their current activities.

## B. Qualifications

Describe in complete detail of the Respondent's organization's qualifications in a clinical chemistry laboratory that performs at least 25,000 specimens a year, to undertake the proposed work.

### **C. Technical Approach**

Respondent must include their Technical Approach which will include the following elements:

- 1) Present separate workflows using diagrams and narrative descriptions specific to your laboratory for both newborn and prenatal screening operations including, but not limited to, projected daily work schedules showing estimated start times and completion times for each test and the overall time flow diagram for daily operations; with integration of the activities for newborn and prenatal screening; and the interrelationship of test schedules for efficiency.
- 2) Describe in detail the actual procedure(s) that will be used to receive newborn and prenatal specimens from U.S.P.S., Golden State Overnight (GSO) or courier at the Contractor's laboratory site.
- 3) Describe in detail the actual method(s) that will be used for transmission of prenatal screening specimens from designated P.O. Box(es) to the Contractor's laboratory site. The CDPH will obtain and pay for P.O. Box(es) to be used specifically and only for receipt of prenatal screening specimens. The CDPH will pay for postage and the Permit in Business Reply. Exhibit XVII, Program Appendices, Appendix 12, List of U.S.P.S. PO Boxes identifies the locations of the designated PO Boxes by region. The CDPH will pay for GSO services for the transport of newborn specimens. The Contractor may use a medical courier to transport the newborn or prenatal specimens but at Contractor's own expense. If Contractor chooses to use a medical courier to transport newborn or prenatal specimens, Contractor must describe in detail the actual procedure(s) that will be used to transport and receive those specimens via medical courier at Contractor's own expense.

Include a sample of the Contractor's Newborn Specimen Transport Logs that the Contractor plans to use to track specimens and to locate any missing specimens. Describe in detail the procedures to be used for distribution of the transport logs to the hospitals in the region and for reconciling newborn screening specimens received with those listed on the specimen transport log.

- 4) Complete sample accessioning and data entry procedures.
- 5) Provide a schedule to complete tests efficiently.
- 6) Meet the transportation requirements for specimens from the designated P.O. Boxes.
- 7) Maintain equipment.
- 8) Plan for proper reagent preparation/labeling.
- 9) Plan to troubleshoot and record corrective actions.
- 10) Plan to assure proper hazardous waste disposal.
- 11) Plan to sort samples for each specific trimester before testing.

### **D. Management Plan**

Respondent must include their Management Plan which will include the following elements:

- 1) A complete and detailed timetable that the prospective NAPS Contractor expects to

follow in order to be ready to assume testing for the geographical area for which the proposal is submitted, with assurances that actual testing of patient specimens will begin after **July 1, 2014**. The timetable shall include assembly of all staff by recruitment or reassignment for participation in training provided by CDPH in **Richmond**, beginning **July 1, 2014** for up to four (4) consecutive weeks, Monday through Friday, 8 a.m. to 5 p.m. daily; and the testing of practice specimens provided by GDSP beginning around **August 4, 2014** for approximately a two (2) month period.

- 2) Detailed plan and schedule for assuring that contractor will provide seven-days-a-week Contractor operation, including holidays, with an on-site Contractor supervisor who qualifies as a clinical laboratory general supervisor under the CLIA regulation.
- 3) Detailed written descriptions of the Contractor's plans for maintaining the quality of results using CDPH-developed procedures for testing genetic diseases as described in Section XIV, Sample Contract Forms/Exhibits, Exhibit A, Subsection 5, Services to be Performed.
- 4) Detailed plan for handling overload testing capability of 50% for a period up to 30 days; i.e., reagent inventory, personnel, etc., for newborn screening and prenatal screening.
- 5) Detailed plan for maintaining communication with CDPH to report and resolve problems and to report status of ongoing operations.
- 6) Detailed plan to assure that on-site laboratory supervisors keep Contractor management abreast of all Contractor operations, including, but not limited to, problems related to workflow, proficiency testing, equipment failure, and completion of tests.
- 7) Detailed plan to assure that all Contractor personnel are properly trained in equipment usage and other procedures, including, but not limited to, test methods and reporting, equipment maintenance and troubleshooting, and data entry. Include a training plan for new personnel to be hired during the term of the contract.
- 8) Detailed plan to assure the uninterrupted supply of trained Contractor personnel for newborn screening and prenatal screening (e.g., supervisors, analysts, data entry operators, etc.).
- 9) Detailed plan to provide employee oversight, supervision, and problem resolution.
- 10) Detailed plan to assure adequate supply by **July 1, 2014**, of all equipment items and consumables needed to perform the scope of work which are not provided by the CDPH, for newborn screening and prenatal screening.
- 11) Detailed plan to assure uninterrupted supply of all equipment items and consumables not provided by the CDPH, for newborn screening and prenatal screening.
- 12) Detailed plan to provide and ensure quality control of analytic results and data entry including, but not limited to: timeliness of data entry; monitoring of the work to assure conformance to the standard set forth in Section XV, Program Appendices, Appendix 5, Laboratory Protocols consisting of A - O; and training and continuous evaluation of data entry personnel.
- 13) Detailed plan to monitor and assure the timely reporting to the appropriate CDPH-designated area genetic centers of all initial positive results for primary congenital hypothyroidism, congenital adrenal hyperplasia, biotinidase deficiency, galactosemia



and urgent disorders identified through MS/MS. Initial positives for hemoglobinopathies, cystic fibrosis, SCID and prenatal are reported by the CDPH.

- 14) Timetable for implementation to begin testing.
- 15) Plan and schedule for routine operation and presence of supervision staff.
- 16) Plan to assure proper training of all Contractor personnel and ensure an uninterrupted supply of personnel.
- 17) Plan to monitor and report Contractor expenses.

## **E. Contractor Personnel**

The Respondent will need to submit Contractor Personnel information which includes the following information:

- 1) Description of the qualifications and pertinent experience of the Laboratory Director responsible for operation of all screening activities. Include the title, level of training, including education and licensing, and job description of the Laboratory Director. The qualifications and experience must be in a clinical chemistry laboratory that performs at least 25,000 specimens a year.
- 2) Description of the qualifications and pertinent experience of supervisory personnel. Include the title, level of training, including education and licensing, and job description of all supervisory personnel. The qualifications and experience must be in a clinical chemistry laboratory that performs at least 25,000 specimens a year.
- 3) Description of the qualifications and pertinent experience of the analysts and support staff. Include the number of analysts and laboratory assistants. Include the classification or position titles and levels of personnel to be employed to perform clinical laboratory testing and support services.
- 4) Description of prior history of your laboratory staff serving as Contractor to CDPH to perform genetic disease testing.

## **F. Facilities/Site Visit**

After proposal opening, the Evaluation Committee will contact the Respondent to schedule the Site Visit to verify the facility provided by the Respondent is in accordance with the specifications outlined in this solicitation. The Key Staff Interviews may occur on the same date as the Site Visit. Those Respondents with at least 250 points after the scoring of the Executive Summary, Qualifications, Technical Approach, Management Plan, and Contractor Personnel will have their sites visited. Any Respondents with less than 250 points after the scoring of the Executive Summary, Qualifications, Technical Approach, Management Plan, and Contractor Personnel will not be scheduled for Key Staff Interviews and will have their Site Visit cancelled.

At the Site Visit, the Evaluation Committee will verify that the space and physical resources required in this solicitation are in place. The space and physical resources required for the facility are found in Section V, Respondent's Response Requirements, Subsection F, Facilities/Site Visit and Section XV, Program Appendices, Appendix 6, Newborn and Prenatal Screening Laboratory Specifics. The Respondent's response will include the following facility's information:

- 1) Describe in complete detail: space, facilities and physical resources actually available for this work in the laboratory, including office space and storage space; floor space; bench or table top; shelves; equipment; records; plumbing capacity;

glassware prep and wash; safety measures; disposal areas. Provide a detailed drawing to scale, which shows location and relationships of furniture, facilities and equipment. Respondent should include a detailed drawing to scale showing specimen sorting area, data entry area, reagent storage area and placement of equipment and supplies needed to perform the screening activities (including SCID test) with the proposal. Respondent must include description of temperature and humidity control for laboratory areas. The Evaluation Committee will also evaluate the storage for refrigerated reagent kits and specimens. All the space and physical resources required for the facility are found in Section XV, Program Appendices, Appendix 6, Newborn and Prenatal Screening Laboratory Specifics and must be included in the description and the drawing.

## **G. Key Staff Interview**

Key Staff are defined as the Laboratory Director and Supervisory Personnel. After proposal opening, the Evaluation Committee will contact the Respondent to schedule an interview with the Key Staff named in this solicitation. The Key Staff Interviews may occur on the same date as the Site Visit. Those Respondents with at least 250 points after the scoring of the Executive Summary, Qualifications, Technical Approach, Management Plan, and Contractor Personnel will be scheduled for Key Staff Interviews. Any Respondents with less than 250 points after the scoring of the Executive Summary, Qualifications, Technical Approach, Management Plan, and Contractor Personnel will have their Interview cancelled.

The named Key Staff proposed in this IS must be available to attend the face to face interview. The Key Staff Interview will consist of detailed questions designed to verify the qualifications, experience, and capabilities of the proposed Contractor team members.

## **VI. Format Requirements**

### **A. Format requirements**

Submit one (1) original, signed proposal response, three (3) signed proposal response copies, and one soft copy. The soft copy must be prepared and saved using Microsoft Office tools and on one or more non-rewritable CDs.

- a) Write "Original" on the original proposal response.
- b) Each proposal response is to be complete with a copy of all required attachments and documentation.

## **VII. Additional Response Requirements**

This Informal Solicitation and the Respondents proposal response will be made part of the CDPH's final contract. The following contents must be included with your response:

- A.** Responses must contain all requested information and conform to the format described in this section. It is the Respondent's responsibility to provide all necessary information for CDPH to evaluate the responses, verify requested information and determine the Respondent's ability to perform the tasks and activities as defined in the Section XIV, Sample Contract Forms/Exhibits, Exhibit A, Scope of Work.
- B.** At least two (2) consecutive years of experience of the type(s) listed in Section V, Respondent's Response Requirements, Subsection E, Contractor Personnel. All experience must have occurred within the past five years. Respondents must have a past record of sound business integrity and history of being responsive to past contractual obligations.

- C. Per the California Laboratory License Requirement, respondents must submit a copy of the current California Laboratory License, and the Laboratory must be located in the region it will serve.
- D. Provide a current copy of California Secretary of State Certification to do business with the State of California.
- E. Complete and return requested copy of the STD 204, Payee Data Record, and the CCC 307, Contractor's Certification Clause form, included in Section XIII, Attachments/ Sample Exhibits/Appendices, Attachments 3 and 4 respectively.
- F. The Technical Proposal must include a table of contents outlined with the evaluation categories, and all pages must be numbered sequentially.

**G. Cost Proposal:**

The respondent must submit the Response Form listed in Section XIII, Attachments/Sample Exhibits/Appendices, Attachment 1. The respondent must also submit the Cost Proposal Summary and Instructions, Section XIII, Attachments/Sample Exhibits/Appendices, Attachment 1A. Rates are to be submitted based on testing estimated births and estimated participation of pregnant women for the Laboratory area.

**H. The cost is stated in the following terms:**

1. The proposed cost per completed newborn screening panel.
2. The proposed cost per completed prenatal screening panel.
3. The respondent must state separate costs for each fiscal period, of the contract term. The fee per panel shall be rounded to the nearest cent.
4. The proposed One-Time-Start-Up Costs.

**VIII. Submission Information**

	Required Documentation	Instructions	Pass/Fail
1	Response Form (Section XIII, Attachment 1)	Complete and return one copy of the Response form entirely. Initial any changes/corrections made on this form.	
2	Cost Proposal Summary and Instructions (Section XIII, Attachment 1a)	Complete and return one copy of the Cost Proposal Summary in its entirety with the Proposals Cost.	
3	Required Attachment/ Certification Checklist (Section XIII, Attachment 2)	Complete and return one copy of the Certification Checklist. Check each item with "Yes" or "N/A", as applicable, and sign the form. If necessary, explain your firm's responses.	
4	Payee Data Record STD 204 (Section XIII, Attachment 3)	Complete and return one copy of the form <u>only</u> if your firm has not previously entered into a contract with CDPH. If uncertain, complete and return the form.	

	Required Documentation	Instructions	Pass/Fail
5	CCC 307 – Certification (Section XIII, Attachment 4)	Complete and return one copy of this form indicating your firm’s willingness and ability to comply with the Contractor Certification Clauses appearing in this attachment. The attachment supplied in this solicitation represents only a portion of the information in this document. Visit this web site to view the entire document:  <a href="http://www.ols.dgs.ca.gov/Standard+Language/default.htm">http://www.ols.dgs.ca.gov/Standard+Language/default.htm</a> .	
6	Oath of Confidentiality (Section XIII, Attachment 5)	Complete and return one copy of this form.	
7	Client References (Section XIII, Attachment 6)	Complete and return one copy of this form listing three clients that have been served by your firm within the past five years whose needs were in a clinical chemistry laboratory that performs at least 25,000 specimens a year. List the most recent first.	
8	Business Information Sheet (Section XIII, Attachment 7)	Complete, sign and return one copy of this form.	
9	Darfur Contracting Act (Section XIII, Attachment 8)	Complete and return one copy of this form <u>only</u> if the responding firm is based in California and the total cost quote is \$100,000 or more.	
10	Iran Contracting Act (Section XIII, Attachment 9)	Complete and return one copy of this form <u>only</u> if the responding firm is based in California and the total cost quote is \$1,000,000 or more.	
11	Licensure Information Sheet (Section XIII, Attachment 10)	Complete and return one copy of this form.	
12	DVBE Participation Instructions (Section XIII, Attachment 11)	Review the DVBE Participation Instructions in its entirety. Nothing needs to be returned.	
13	Actual DVBE Participation (Section XIII, Attachment 11a)	List your actual DVBE participation if applicable.	
14	DVBE Incentive Instructions (Section XIII, Attachment 11b)	Review the instructions in its entirety. Nothing needs to be returned.	
15	DVBE Incentive Request (Section XIII, Attachment 11c)	Review and if needed, fill out the DVBE Incentive Request in its entirety.	
16	DVBE Subcontractor/Supplier Acknowledgement (Section XIII, Attachment 11d)	Review and if needed, fill out the DVBE Subcontractor/Supplier Acknowledgement in its entirety.	
17	Small Business Subcontractor/Supplier Acknowledgement	Review the Small Business Subcontractor/Supplier Acknowledgement in its entirety.	

	Required Documentation	Instructions	Pass/Fail
	(Section XIII, Attachment 12)		
18	Business License (To be provided by Respondent)	All businesses <u>must</u> submit a copy of a current business license issued by the governmental jurisdiction in which the business is located. Submit an explanation if this documentation cannot be supplied or there is reason to believe no license is required.	
19	Proof of Corporation status <b>(Corporations Only)</b> (To be provided by Respondent)	Corporations must either submit a copy of the Responding laboratory's most current Certificate of Status issued by the State of California, Office of the Secretary of State <u>or</u> submit a downloaded copy of the Responding laboratory's on-line status information from the California Business Portal website of California's Office of the Secretary of State. Submit an explanation if you cannot submit this documentation. Unless otherwise specified, do not submit copies of your laboratory's Bylaws or Articles of Incorporation	
20	Proof of Non-profit status <b>(Non-profit Organizations Only)</b> (To be provided by Respondent)	Non-profit organizations must submit a copy of a current IRS determination letter indicating nonprofit or 501(3) (c) tax exempt status.	
21	California Laboratory License (To be provided by Respondent)	Laboratories must submit a copy of the current California Laboratory License, and the laboratory must be located in the region served.	
22	CLIA approval and performance information for proficiency test programs (To be provided by Respondent)	Laboratories must submit Clinical Laboratory Improvement Amendments (CLIA) approval and performance information for proficiency test programs in which they are currently enrolled. The Laboratory Director of the laboratory must be licensed by the State of California.	

## IX. General Instructions

- A. Responses are to be submitted in two parts and clearly labeled:
  - 1) Technical Proposal, and
  - 2) Cost Proposal.
- B. Each respondent must submit only one (1) proposal response per region. If a laboratory or individual submits more than one (1) proposal response per region, GDSP will consider all respondent's proposals nonresponsive.
- C. Mail or arrange for hand delivery of the original proposal response and required copies to CDPH's GDSP. Responses may not be transmitted by fax.

- D. GDSP must receive the proposal response, regardless of postmark or method of delivery, by 4:00 p.m. on [March 10, 2014](#). Late proposal responses will not be accepted.
- E. Label and submit the proposal response package using the following methods:

<b>U.S. Mail or Hand Delivery</b>
<b>Informal Solicitation 14-XXXXX</b> California Department of Public Health Attention: Janice Byers Genetic Disease Screening Program 850 Marina Bay Parkway, Room F-175 Richmond, CA 94804  <b>Do Not Open until 3/10/2014</b>

F. Delivery Warning

- 1) CDPH's internal processing of U.S. mail may add up to 48 hours to the delivery time. If the proposal response is mailed, consider using certified or registered mail and request a receipt upon delivery.
- 2) For hand deliveries, allow sufficient time to sign-in at the security desk.
- 3) Proof of timely receipt:
  - i. CDPH staff will date/time stamp the proposal response package/envelope received.
  - ii. To be timely, CDPH must receive the proposal response packages at the stated place of delivery no later than the date and time stated in Section IV, Key Action Dates.
  - iii. CDPH will deem late proposal response packages nonresponsive.

**X. Evaluation and Selection**

Best Values Methodology Evaluation Process

- 1) Shortly after the submission deadline, the Evaluation Committee will review each offer received to determine which packages are complete upon receipt.
- 2) This is an informal solicitation process and CDPH reserves the right to determine if an offer will be rejected if it is incomplete.
- 3) If deemed necessary by CDPH, the Evaluation Committee may collect additional documentation, signatures, missing items, or omitted information during the evaluation process. CDPH will advise the Respondent by email of any documentation that is required and the deadline for the submission of the additional documentation. Failure to submit the required documentation by the date and time indicated may cause CDPH to reject a proposal response from consideration.
- 4) CDPH reserves the right to modify or cancel this solicitation process at any time and may choose not to make an award.

- 5) The following occurrences may cause CDPH to reject a Respondent's proposal response from further consideration. The failure of a Respondent to:
  - i. Meet the stated participation pre-requisites by the submission deadline.
  - ii. Do business in the State of California.
  - iii. Be willing and able to comply with the contract terms, conditions and/or exhibits that will appear in the resulting contract.
- 6) This section describes, in general, the process that GDSP will use to evaluate timely the proposals. The proposals will be evaluated and scored by a GDSP Evaluation Committee. The proposals will be reviewed and scored based upon the adequacy and thoroughness of their response to the IS requirements.
- 7) Each proposal response will be evaluated in the following three areas: Administrative Requirements, Functional Score and Cost Score. Administrative Requirements are evaluated on a Pass/Fail basis. The Functional Score will be scored on the eight weighted evaluation criteria. The Cost Score will be evaluated using the proposed cost. After passing the Administrative Requirements, a Respondent can earn up to a total of five hundred (500) points.
- 8) During the review stage, the Evaluation Committee will verify the claims made by the laboratory to determine if the laboratory's claims are accurate.
- 9) If the materials submitted by a respondent do not prove, support or substantiate the claims made on Section XIII, Attachments/Sample Exhibits/ Appendices, Attachment 2, Required Attachment/Certification Checklist in this IS, the proposal will be deemed non-responsive and rejected from further consideration.
- 10) CDPH will award to the winning Contractor laboratory that has passed all Administrative Requirements and scored the highest points in Functional Score and Cost Score. This winning Contractor laboratory is deemed to supply CDPH with the Best Value proposal response.

## Evaluation Methodology:

Category	Percentage	Maximum Points
Administrative Requirements	n/a	Pass/Fail
<b>Total Administrative Requirements Score</b>	n/a	<b>Pass/Fail</b>
Executive Summary	5%	20
Qualifications (Capabilities)	11%	45
Technical Approach	19%	75
Management Plan	15%	60
Contractor Personnel	16%	65
Facilities Site Visit	19%	75
Key Staff Interviews	15%	60
<b>Total Functional Score</b>	<b>80%</b>	<b>400</b>
Cost Score	20%	100
<b>Total Score (Best Value to the State)</b>	<b>100%</b>	<b>500</b>

### A. Administrative Requirements

This section provides the Administrative Requirements that Respondents must comply with in order to be deemed responsive and responsible. All elements of the Administrative Requirements are scored on a pass or fail basis. If the appropriate documentation listed is submitted as stated by the IS, then the Respondent passes that element of the Administrative Requirements evaluation. If the Respondent does not complete the listed elements of the Administrative Requirements evaluation, then the Respondent fails. Respondents must pass every element scored in the Administrative Requirements to move onto Functional Scoring. Any Respondent not passing every



element of the Administrative Requirements will be deemed non-responsive and disqualified from the evaluation.

- **General Requirements**

The following requirements must be met in order to successfully pass the Administrative Requirements section.

	Instruction	Instructions	Pass/Fail
1	Proposal response Content	Responses are to be submitted in two parts and clearly labeled: a) Technical Proposal, and b) Cost Proposal.	
2	One proposal response per region.	Each respondent must submit only one (1) Response per region. If a laboratory or individual submits more than one (1) response per region, all those responses will be deemed non-responsive and will be rejected.	
3	Proposal response delivery date and time	GDSP must receive the proposal response, regardless of postmark or method of delivery, by 4:00 p.m. on <a href="#">March 10, 2014</a> . Late proposal responses will not be accepted.	

- **Required Forms/Assembly Instructions**

Complete and return **one copy** of each item listed in the following table. Place the documentation in the Appendix Section of your proposal in the order shown below. When completing the attachments, follow the instructions in this section and the instructions appearing on each attachment. Unless otherwise indicated, do not submit supplemental information or other materials that CDPH has not requested. CDPH may choose to set aside or disregard any such material that is submitted.

A person authorized to legally bind the Respondent must sign each attachment, exhibit and additional documentation that requires a signature. All signatures must be in blue ink. After completing and signing the attachments, exhibits and additional documentation identified below, assemble them in the order shown:

The following requirements must be met in order to successfully pass the Administrative Requirements section. Furthermore, the Respondents must complete and return **one copy** of each item listed in this section with their final proposal response. When completing the attachments, follow the instructions in this section and the instructions appearing on each attachment. Unless otherwise indicated, do not submit supplemental information or other materials that CDPH has not requested. CDPH may choose to set aside or disregard any such material that is submitted.

A person authorized to legally bind the Respondent must sign each attachment that requires a signature. All signatures must be in ink and preferably be in a color other than black. After completing and signing the attachments identified below, assemble them in the order shown:

	Required Documentation	Instructions	Pass/Fail
1	Response Form (Section XIII, Attachment 1)	Complete and return one copy of the Response form entirely. Initial any changes/corrections made on this form.	
2	Cost Proposal Summary and Instructions (Section XIII, Attachment 1a)	Complete and return one copy of the Cost Proposal Summary in its entirety with the Proposals Cost.	
3	Required Attachment/ Certification Checklist (Section XIII, Attachment 2)	Complete and return one copy of the Certification Checklist. Check each item with "Yes" or "N/A", as applicable, and sign the form. If necessary, explain your firm's responses.	
4	Payee Data Record STD 204 (Section XIII, Attachment 3)	Complete and return one copy of the form <u>only</u> if your firm has not previously entered into a contract with CDPH. If uncertain, complete and return the form.	
5	CCC 307 – Certification (Section XIII, Attachment 4)	Complete and return one copy of this form indicating your firm's willingness and ability to comply with the Contractor Certification Clauses appearing in this attachment. The attachment supplied in this solicitation represents only a portion of the information in this document. Visit this web site to view the entire document: <a href="http://www.ols.dgs.ca.gov/Standard+Language/default.htm">http://www.ols.dgs.ca.gov/Standard+Language/default.htm</a> .	
6	Oath of Confidentiality (Section XIII, Attachment 5)	Complete and return one copy of this form.	
7	Client References (Section XIII, Attachment 6)	Complete and return one copy of this form listing three clients that have been served by your firm within the past five years whose needs were in a clinical chemistry laboratory that performs at least 25,000 specimens a year. List the most recent first.	
8	Business Information Sheet (Section XIII, Attachment 7)	Complete, sign and return one copy of this form.	
9	Darfur Contracting Act (Section XIII, Attachment 8)	Complete and return one copy of this form <u>only</u> if the responding firm is based in California and the total cost quote is \$100,000 or more.	
10	Iran Contracting Act (Section XIII, Attachment 9)	Complete and return one copy of this form <u>only</u> if the responding firm is based in California and the total cost quote is \$1,000,000 or more.	
11	Licensure Information Sheet (Section XIII, Attachment 10)	Complete and return one copy of this form.	
12	DVBE Participation Instructions (Section XIII, Attachment 11)	Review the DVBE Participation Instructions in its entirety. Nothing needs to be returned.	
13	Actual DVBE Participation (Section XIII, Attachment 11a)	List your actual DVBE participation if applicable.	

	Required Documentation	Instructions	Pass/Fail
14	DVBE Incentive Instructions(Section XIII, Attachment 11b)	Review the instructions in its entirety. Nothing needs to be returned.	
15	DVBE Incentive Request (Section XIII, Attachment 11c)	Review and if needed, fill out the DVBE Incentive Request in its entirety.	
16	DVBE Subcontractor/ Supplier Acknowledgement (Section XIII, Attachment 11d)	Review and if needed, fill out the DVBE Subcontractor/Supplier Acknowledgement in its entirety.	
17	Small Business Subcontractor/ Supplier Acknowledgement (Section XIII, Attachment 12)	Review the Small Business Subcontractor/Supplier Acknowledgement in its entirety.	
18	Business License (To be provided by Respondent)	All businesses <u>must</u> submit a copy of a current business license issued by the governmental jurisdiction in which the business is located. Submit an explanation if this documentation cannot be supplied or there is reason to believe no license is required.	
19	Proof of Corporation status <b>(Corporations Only)</b> (To be provided by Respondent)	Corporations must either submit a copy of the Responding laboratory's most current Certificate of Status issued by the State of California, Office of the Secretary of State <u>or</u> submit a downloaded copy of the Responding laboratory's on-line status information from the California Business Portal website of California's Office of the Secretary of State. Submit an explanation if you cannot submit this documentation. Unless otherwise specified, do not submit copies of your laboratory's Bylaws or Articles of Incorporation	
20	Proof of Non-profit status <b>(Non-profit Organizations Only)</b> (To be provided by Respondent)	Non-profit organizations must submit a copy of a current IRS determination letter indicating nonprofit or 501(3) (c) tax exempt status.	
21	California Laboratory License (To be provided by Respondent)	Laboratories must submit a copy of the current California Laboratory License, and the laboratory must be located in the region served.	
22	CLIA approval and performance information for proficiency test programs(To be provided by Respondent)	Laboratories must submit Clinical Laboratory Improvement Amendments (CLIA) approval and performance information for proficiency test programs in which they are currently enrolled. The Laboratory Director of the laboratory must be licensed by the State of California.	

## B. Functional Score and Cost Score Evaluation and Selection Process

In reviewing the Functional Score areas, the Evaluation Committee may consider issues including, but not limited to, the extent to which a laboratory response:

- Is lacking information, lacking depth or breadth or lacking significant facts and/or details.
- Is fully developed, comprehensive and has few (if any weaknesses), defects or deficiencies.
- Demonstrates that the laboratory understands GDSP's needs, the services sought, and the contactor's responsibilities.
- Illustrates the laboratory's capability to perform all services and meet all scope of work requirements.
- Demonstrates the applicant's capacity and commitment to exceed regular services needed (i.e., enhanced features, approaches, or methods and creative or innovative business solutions).

Each proposal response to this IS will be reviewed for responsiveness to the requirements stated in the IS. Proposal responses will only be evaluated based on the information provided. Respondents should ensure that all relevant information is fully and completely provided for the Evaluation Committee to consider. If a proposal response is missing required information, it may be deemed non-responsive.

Award of the IS will be based on a best value method evaluation process that includes cost as a substantial factor in the selection process. As a result, the winning contractors overall approach and cost provides the best value. The following table shows all elements of scoring and the total possible points for each section.

Functional Score Category		Total Possible	Respondent Score
<b>Executive Summary</b>			
To what extent does the Respondent summarize the role of a NAPS Laboratory and describe how contract activities fit into the Respondent's current activities and goals.			
<b>Total Executive Summary Score</b>		<b>20</b>	
<b>Qualifications (Capabilities)</b>			
To what extent does the Respondent adequately demonstrate qualifications and capabilities to perform the services sought? Consider the Respondent's past experience and work in a clinical chemistry laboratory that performs at least 25,000 specimens a year.			
<b>Total Qualifications Score</b>		<b>45</b>	
<b>Respondent Technical Approach</b>			
To what extent does the Respondent adequately demonstrate the capacity to:			
1	Complete sample accessioning and data entry procedures.	10	
2	Provide a schedule to complete tests efficiently.	10	
3	Meet the transportation requirements for specimens.	10	
4	Maintain equipment listed in Section XV, Program Appendices, Appendix 7.	5	
5	Plan for proper reagent preparation/labeling/storage.	10	

Functional Score Category		Total Possible	Respondent Score
6	Plan to troubleshoot and record corrective actions.	10	
7	Plan to assure proper hazardous waste disposal.	10	
8	Plan to sort samples for each specific trimester before testing and storage of samples after testing	10	
<b>Total Respondent Technical Approach Score</b>		<b>75</b>	
<b>Management Plan</b>			
	Rate the effectiveness of each of the following:		
1	Timetable for implementation to begin testing.	7	
2	Plan and schedule for routine operation and presence of supervision staff.	7	
3	Plan for communication with GDSP to report and resolve problems.	5	
4	Plan for supervisors to keep laboratory management informed of laboratory operations and problems.	5	
5	Plan to assure proper training of all Contractor personnel and ensure an uninterrupted supply of personnel.	7	
6	Plan for employee oversight and supervision.	5	
7	Plan for uninterrupted supply of all items contractor must provide.	5	
8	Plan for quality control of data entry and analytic results.	7	
9	Plan to monitor and assure timely reporting of presumptive positive results.	7	
10	Plan to monitor and report Contractor expenses.	5	
<b>Total Management Plan Score</b>		<b>60</b>	
<b>Contractor Personnel</b>			
	Rate the effectiveness of each of the following:		
1	Description of the qualifications and pertinent experience of the Laboratory Director responsible for operation of all screening activities. Include the title, level of training, including education and licensing, and job description of the Laboratory Director. The qualifications and experience must be in a clinical chemistry laboratory that performs at least 25,000 specimens a year.	15	
2	Description of the qualifications and pertinent experience of supervisory personnel. Include the title, level of training, including education and licensing, and job description of all supervisory personnel. The qualifications and experience must in a clinical chemistry laboratory that performs at least 25,000 specimens a year.	15	
3	Description of the qualifications and pertinent experience of the analysts and support staff. Also, include the number of analysts and support staff. Include the classification or position titles and levels of personnel to be employed to perform testing and support services. The qualifications and experience must in a clinical chemistry laboratory that performs at least 25,000 specimens a year.	15	
4	Description of prior history of Contractor personnel in	20	

Functional Score Category		Total Possible	Respondent Score
	your laboratory as Laboratory Personnel in a clinical chemistry laboratory that performs at least 25,000 specimens a year.		
<b>Total Contractor Personnel Score</b>		<b>65</b>	
<b>Facilities Site Visit</b>			
	<p>At the Site Visit, the Evaluation Committee will verify that the space and physical resources required in this solicitation are in place. The space and physical resources required for the facility are found in Section V, Subsection F, Facilities/Site Visit and Section XV, Appendix 6, Newborn and Prenatal Screening Laboratory Specifics. The Respondent will include facilities information which will include the following information which will be verified at the Site Visit:</p> <p>Describe in complete detail: space, facilities and physical resources actually available for this work in the laboratory, including office space and storage space; floor space; bench or table top; shelves; equipment; records; plumbing needs; glassware prep and wash; safety measures; disposal areas. Provide a detailed drawing to scale, which shows location and relationships of furniture, facilities and equipment. Respondent should include a detailed drawing to scale showing specimen sorting area, data entry area, reagent storage area and placement of equipment and supplies needed to perform the screening activities (including SCID test) with the proposal. Respondent must include description of temperature and humidity control for laboratory areas. The Evaluation Committee will also evaluate the storage for refrigerated reagent kits and specimens. The space and physical resources required for the facility found in Section V, Subsection F, Facilities/ Site Visit and Section XV, Appendix 6, Newborn and Prenatal Screening Laboratory Specifics must be included in the description and the drawing.</p>	75	
<b>Total Facilities Site Visit Score</b>		<b>75</b>	
<b>Key Staff Interviews</b>			
	Those Respondents with at least 250 points after the scoring of the Executive Summary, Qualifications, Technical Approach, Management Plan, and Contractor Personnel will be scheduled for Key Staff Interviews. The named Laboratory Director and Supervisors must be available to attend the face-to-face interview with the Evaluation Committee. The Key Staff Interview may occur at the same date of the site visit. The Key Staff Interview will be scheduled soon after proposals are received by CDPH. The Key Staff Interview will consist of detailed questions designed to verify the qualifications, experience, and capabilities of the proposed Contractor team.	60	
<b>Total Key Staff Interview Score</b>		<b>60</b>	

Functional Score Category		Total Possible	Respondent Score
<b>Total Functional Score</b> (Sum of Executive Summary, Qualifications, Technical Approach, Management Approach, Contractor Personnel, Facilities and Key Staff Interview)		<b>400</b>	
<b>Cost</b>			
	The responding contractor's costs and rates shall comply with the instructions in the Cost Proposal Summary for all three (3) years.	100	
<b>Total Cost Score</b>		<b>100</b>	
<b>Total Score</b> (Best Value to the State)		<b>500</b>	

### C. Preference Programs

To confirm the identity of the lowest responsive and responsible Respondent, CDPH will adjust the total proposal cost for applicable claimed preference(s). CDPH will apply preference adjustments to eligible Respondents according to State regulations following verification of eligibility with the appropriate office of the DGS.

#### 1. Small/Micro Business Preference (preference not to exceed \$50,000)

- 1) A responsive bidder, certified as a small/micro business in a relevant business category or type, will be granted a preference up to five percent (5%) of the lowest responsive bid. Small business means a responsive/responsible bidder that is certified by the DGS as a small business or micro business.
- 2) In granting small/micro business preference, no bid price will be reduced by more than five percent (5%). The cost adjustment is for computation purposes only and does not alter the actual cost offered by the bidder.
- 3) To be certified as a California small/micro business and eligible for a bidding preference the business concerned must meet the state's eligibility requirements and must have submitted an application for small/micro business status no later than 4:00 p.m. on the bid submission deadline.
- 4) Firms desiring small/micro business certification must obtain the Small Business Certification Application (i.e., STD 812 or other form) from DGS, OSDS, fully complete the application, and submit it to DGS as instructed in the application. Prospective bidding firms desiring small business certification assistance, may contact the Department of General Services by the following means:
  - a. (916) 322-5060 (24 hour recording and mail requests), or
  - b. (916) 375-4940 (Small business assistance) or (800) 559-5529 (live operator-central receptionist), or
  - c. Internet address: [www.pd.dgs.ca.gov/smbus/getcertified.htm](http://www.pd.dgs.ca.gov/smbus/getcertified.htm) or
  - d. Fax: (916) 375-4950, or
  - e. Email: [OSDSHelp@dgs.ca.gov](mailto:OSDSHelp@dgs.ca.gov)

## 2. Disabled Veteran Business Enterprise (DVBE) Response Incentive

In accordance with Section 999.5(a) of the Military and Veterans Code, an incentive will be given to bidders who provide DVBE participation. For evaluation purposes only, CDPH shall apply an incentive to bids that propose California certified DVBE participation as identified on **Bidder Declaration** and confirmed by CDPH. The incentive amount for awards based on low price will vary in conjunction with the percentage of DVBE participation.

NOTE: When used in combination with a preference adjustment, the cumulative adjustment amount cannot exceed 10% or \$100,000, whichever is less.

CONFIRMED DVBE PARTICIPATION OF:	DVBE INCENTIVE:
3% and above	(5% of 100) = 5
2% to 2.99%	(3% of 100) = 3
1% to 1.99%	(1% of 100) = 1

The net proposal cost of responsible Responses will be reduced (for evaluation purposes only) by the amount of DVBE incentive as applied to the lowest responsible net proposal cost. If the number 1 ranked responsive, responsible Respondent is a California-certified small business, the only Respondents eligible for the incentive will be California-certified small businesses. The incentive adjustment for awards based on low cost cannot exceed 5% or \$100,000, whichever is less, of the number 1 ranked net proposal cost. When used in combination with a preference adjustment, the cumulative adjustment amount cannot exceed 5% or \$100,000, whichever is less.

### D. Cost Score and Point Allocation

The Cost Score of each Response's Final Proposal will be determined after any adjustments as described in Section X, Evaluation and Selection, Subsection 2, Functional Score and Cost Score Evaluation and Selection Process. Once the Total Functional Score and the Costs Score are calculated, the Evaluation Committee will calculate the Total Score for each responsive and responsible Respondent to the nearest hundredth of a point.

The Cost Score represents 20% of the total points attainable in the IS evaluation process. The maximum Cost Score is 100 points.

All proposal response Cost Scores are based on the ratio of the lowest costs proposal to the Respondents cost proposal multiplied by 100 points, as shown below.

$$\frac{\text{Lowest Proposal Cost}}{\text{Respondents Proposal Cost}} \times 100 = \text{Respondents Cost Score}$$

Example 1 illustrates how DVBE incentives and Small Business Preferences would be applied. In the example, Respondent B initially has the most points (480 total score (functional and cost). As the only small business, Respondent C earns the 5% small business preference, which is applied to the total score (accumulated functional and cost points, prior to incentives and preferences). Respondents A and B earn DVBE preference points and Respondent B has the highest total points after applying the DVBE incentive of 5% (resulting from confirmed DVBE participation of 3% or above). In this example Respondent B would be awarded the contract.



**Example 1. Example Proposal Response Points with Small Business Preference and DVBE Incentive Applied**

Respondent	Meets Small Business Requirement?	Functional Score (W)	Cost Score (X)	Total Score before Incentives (H)	Small Business Preference Points $(H \times 0.05) = S$	Total Points w/ Small Bus $= (W + X + S)$	DVBE INCENTIVE % from Table 1 (Y)	DVBE incentive points $(Z) = (X * Y)$	Total Score
A	no	385	90	475		475	3%	2.7	477.7
B	no	380	100	480		480	5%	5	485
C	yes	350	80	430	21.5	451.5	1%	0.8	473.8

## **XI. Contract Award**

Following the evaluation and selection process of the respondent's informal solicitation, all awardees will be informed of their status. CDPH anticipates notification of the successful awardees by email or postal mail by **April 15, 2014**.

## **XII. Contract Terms and Conditions**

The winning Contractor laboratory must enter an agreement that may contain the Respondent's rate per specimen summary form or budget, a Scope of Work, standard contract provisions, and one or more of the contract forms and/or exhibits identified below. Other exhibits, not identified herein, may also appear in the resulting agreement.

The exhibits identified in this section contain contract terms that require strict adherence to various laws and contracting policies. A Respondent's unwillingness or inability to agree to the terms and conditions shown below or contained in any exhibit identified in this Informal Solicitation may cause GDSP to deem a Respondent non-responsible and ineligible for an award. GDSP reserves the right to use the latest version of any form or exhibit listed below in the resulting agreement if a newer version is available.

In general, GDSP will not accept alterations to the Section XIV, Sample Contract Forms/Exhibits, Exhibit C, General Terms and Conditions (GTC 610), Exhibits D(S), Special Terms and Conditions, and Exhibit A, Scope of Work. GDSP will not accept alternate contract/exhibit language submitted by a prospective respondent. GDSP will consider a proposal containing such provisions "a counter proposal" and GDSP shall reject such a proposal.

### **A. Dispute Resolution**

The parties acknowledge and agree that certain problems or issues may arise, and that such matters shall be brought to CDPH's attention. Problems or issues shall normally be reported in regular status reports or in-person meetings. However, there may be instances where the severity of the problem justifies escalated reporting. To this extent, the Evaluation Committee Team shall determine the level of severity, and notify the appropriate CDPH and GDSP personnel. The personnel notified, and the time period taken to report the problem or issue shall be at a level commensurate with the severity of the problem or issue. The personnel include, but are not limited to the following:

- First Level, Genetic Disease Screening Laboratory Director
- Genetic Disease Screening Program Assistant Division Chief

### **XIII. Attachments/Sample Exhibits/Appendices**

Please see the corresponding section on this webpage to link to all attachments, exhibits and appendices for this Informal Solicitation. The following is a list by name of all incorporated documents:

**ATTACHMENT 1 – Response Form**

**ATTACHMENT 1a – [Use region-specific](#) interactive Excel spreadsheet for this Cost Proposal Summary.**

**ATTACHMENT 2 – Has been removed from the bid package**

**ATTACHMENT 3 – Payee Data Record**

**ATTACHMENT 4 – CCC 307 – Certification**

**ATTACHMENT 5 – Oath of Confidentiality**

**ATTACHMENT 6 – Client References**

**ATTACHMENT 7 – Business Information Sheet**

**ATTACHMENT 8 – Darfur Contracting Act**

**ATTACHMENT 9 – Iran Contracting Act**

**ATTACHMENT 10 – Licensure Information Sheet**

**ATTACHMENT 11 – DVBE Participation Instructions**

**ATTACHMENT 11a – Actual DVBE Participation**

**ATTACHMENT 11b – DVBE Incentive Instructions**

**ATTACHMENT 11c – DVBE Incentive Request**

**ATTACHMENT 11d – DVBE Subcontractor/Supplier Acknowledgement**

**ATTACHMENT 12 – Small Business Subcontractor/Supplier Acknowledgement**

#### **XIV. Sample Contract Forms / Exhibits**

**EXHIBIT A1 – Standard Agreement**

**EXHIBIT A – Scope of Work**

**EXHIBIT B – Budget Detail and Payment Provisions**

**EXHIBIT C – General Terms and Conditions (GTC 610).**

View or download at this Internet site:

<http://www.documents.dgs.ca.gov/pd/traffic/wsca/participatingaddendum/UPSGTC610.pdf>

**EXHIBIT D(S) – Special Terms and Conditions**

View or download Exhibit D(S) at this Internet site:

<http://cdphintranet/FormsPubs/Pages/ContractsForms.aspx>

**EXHIBIT E – Additional Provisions**

**EXHIBIT F—Contractor’s Release**

**EXHIBIT G—Information Privacy and Security Requirements**

**EXHIBIT H—Travel Reimbursement Information**

**EXHIBIT I—Contractor Equipment Purchased with CDPH Funds**

**EXHIBITJ—Letter of Intent to Bid**

##### **1. Additional Incorporated Exhibits**

The following documents and any subsequent updates are not attached, but are incorporated herein and made a part hereof by this reference. These documents may be updated periodically by California Department of Public Health (CDPH), as required by program directives. CDPH shall provide the Contractor with copies of said documents and any periodic updates thereto, under separate cover. CDPH will maintain on file, all documents referenced herein, and subsequent updates.

- A. Appendix 1, entitled Sample Test Request Form (TRF), Newborn Screening.
- B. Appendix 2, entitled Sample Test Request Form, 1<sup>st</sup> Trimester Screening.
- C. Appendix 3, entitled Sample Test Request Form, 2nd Trimester Screening.
- D. Appendix 4, entitled Regional Division by County.
- E. Appendix 5, entitled Laboratory Protocols consisting of A – O.
- F. Appendix 6, entitled Newborn and Prenatal Screening Laboratory Specifics
- G. Appendix 7, entitled List of Major Equipment, Reagents, and Consumables to be supplied by CDPH.

- H. Appendix 8, entitled List of Major Equipment, Reagents, and Consumables to be provided by Contractor.
- I. Appendix 9, entitled Data Entry and Follow-up Actions for Newborn and Prenatal Screening.
- J. Appendix 10, entitled Newborn Screening Specimen Adequacy.
- K. Appendix 11, entitled Confirmation of Contact Entry.
- L. Appendix 12 – List of U.S.P.S. PO Boxes.
- M. Appendix 13 – Invoice Template for Specimen Screening.
- N. Appendix 14 –SCID Protocol 2013.
- O. Appendix 15 – Space Requirements for SCID Assay
- P. Appendix 16 – Required Validation Activities